



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

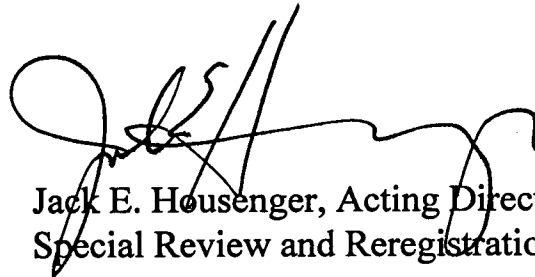
The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Prevention, Pesticides
and
Toxic Substances

November 1, 1999

Memorandum

Subject: **Phosalone:** Reregistration Eligibility Decision Residue Chemistry Chapter.
PC Code: 097701; Case No. 0027. DP Barcode: D256367.

From: Kristina A. EL-Attar, Environmental Protection Specialist
Reregistration Branch 1
Health Effects Division (7509 C)

Through: William J. Hazel, Chemist
Reregistration Branch 1
Health Effects Division (7509 C)
&
Whang Phang, Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509 C)

To: William J. Hazel, Risk Assessor
Reregistration Branch 1
Health Effects Division (7509 C)
&
Deanna Scher, PM Team Reviewer
Special Review and Reregistration Division (7508 W)

Attached is the Residue Chemistry Chapter of the Reregistration Eligibility Decision (RED) document prepared by Reregistration Branch 1 (RRB1) of the Health Effects Division (HED). This review was written by Dynamac Corporation, an EPA contractor, and has been modified by HED to reflect current Agency policies. It has undergone secondary review by the Exposure Team (Expo Team) of RRB1 and HED's Chemistry Science Advisory Council (Chem SAC).

Rhône-Poulenc Ag Company (RPAC) intends to support tolerances for phosalone residues in/on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and

plums) to permit the legal importation of these commodities into the U.S. Registrations of phosalone were withdrawn in the U.S. by the registrant in 1989. In response to the Agency's proposal to revoke tolerances for pesticides with no active domestic registrations, RPAC requested that the Agency maintain import tolerances on the above mentioned commodities of interest. Phosalone is, hence, being considered by the Branch for purposes of tolerance reassessment and risk assessment.

Additional product chemistry data are required concerning beginning materials, discussion of the formation of impurities, and UV/visible absorption. Provided that the registrant submits the data required for the Phosalone TGAI and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Branch has no objections to the reregistration of phosalone with respect to product chemistry data requirements.

Reregistration in regards to tolerance reassessment can only occur, however, once additional field trials reflecting the French use pattern on grapes and the Canadian use pattern on grapes, apples, pears, cherries and peaches are completed; field trial data and directions for use information for plums are submitted; and labels for non-EU countries, which fail to indicate the number of maximum applications of phosalone on pome and stone fruits, (e.g. Turkey, Czech Republic, and Slovak Republic) are revised.

cc: **Deanna P. Scher**, Review Manager, Special Review and Reregistration Division, Office of Pesticide Programs;
William J. Hazel, Risk Assessor, Health Effects Division, Office of Pesticide Programs;
Kristina A. EL-Attar, Environmental Protection Specialist, Health Effects Division, Office of Pesticide Programs

PHOSALONE
PC Code 097701; Case No. 0027

**Reregistration Eligibility Decision:
Product Chemistry Considerations**

August 9, 1999

Contract No. 68-W-99-053

**Submitted to:
U.S. Environmental Protection Agency
Arlington, VA**

**Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268**

PHOSALONE

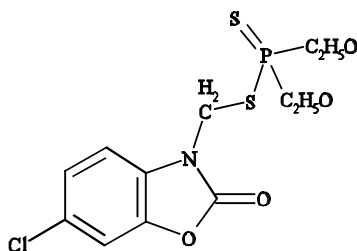
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 097701; Case No. 0027

DESCRIPTION OF CHEMICAL

Phosalone [S-6-(chloro-3-(mercaptomethyl)-2-benzoxazolinone) O,O-diethyl phosphorodithioate] is an acaricide/insecticide for which Rhone-Poulenc is supporting only foreign uses and import tolerances in/on almonds, apricots, apples, cherries, grapes, peaches, pears, and plums/prunes.



Empirical Formula:	C ₁₂ H ₁₅ ClNO ₄ PS ₂
Molecular Weight:	367.8
CAS Registry No.:	2310-17-0
PC Code:	097701

IDENTIFICATION OF ACTIVE INGREDIENT

Phosalone is a powdered solid with a melting point of 40 C, specific gravity of 1.3381 g/mL at 50 C, octanol/water partition coefficient (P_{ow}) of 10230 at 20 C, and vapor pressure of 0.02 mg/m³ at 40 C. Phosalone is practically insoluble in water (1.4 mg/L), but is soluble in acetone, dichloromethane, ethyl acetate, toluene, and methanol at >1000 g/L, n-octanol at 266.8 g/L, and n-heptane at 26.3 g/L.

MANUFACTURING-USE PRODUCTS

According to a search of the Reference Files System (REFS) conducted 7/12/99, there are no

registered manufacturing-use products (MPs) or end-use products (EPs) under PC Code 097701. The single MP that was previously registered, the Rhone-Poulenc 94% T (EPA Reg. No. 359-632) was canceled 4/25/88. Rhone-Poulenc products registered for foreign uses are produced from a 94% TGAI. Only the 94% TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

Data reviewed for the Rhone-Poulenc 94% T (EPA Reg. No. 359-632) in the Phosalone Reregistration Standard dated 3/30/81 were determined be acceptable for most product chemistry data requirements; additional data were required concerning density and solubility (OPPTS 830.7840-7860 and 7300). The Phosalone FRSTR dated 3/17/87 reviewed additional product chemistry data submitted for specific gravity, solubility, and vapor pressure and required additional data. New product chemistry data have since been submitted by Rhone-Poulenc for the 94% TGAI in support of a change in the manufacturing facility and the reregistration of phosalone.

The current status of the product chemistry data requirements for the phosalone 94% TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Most pertinent product chemistry data requirements are satisfied for the Rhone-Poulenc 94% TGAI; additional data are required concerning beginning materials, discussion of the formation of impurities, and UV/visible absorption (OPPTS 830.1600, 1670 and 7050). Provided that the registrant submits the data required in the attached data summary table for the phosalone TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Branch has no objections to the reregistration of phosalone with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode(s): D260636
Subject: Phosalone Product Chemistry Review
From: Kristina A. EL-Attar
To: William J. Hazel
Dated: November 1, 1999
MRID(s): 40901703, 40953401, 44792005-44792007, and 44801001

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

40901703 Seymour, R. (1988) Section A: The Names, Chemical Identity and Composition of Phosalone Technical: Project No. 40321. Unpublished study prepared by Rhone-Poulenc Ag Co. 123 p.

40953401 Chabassol, Y.; Giraud, J.; Picard, C. (1988) Product Chemistry Data: Phosalone: Analysis and Certification of Product Ingredients: Study No. 88-15. Unpublished compilation of Rhone-Poulenc. 163 p.

44792005 Brown, E. (1999) Phosalone Technical Manufacturing Data from Voltas, Ltd: Quality Control Data from 10 Consecutive Batches: Description of the Manufacturing Process: Lab Project Number: RPA/AI/586PHOS: P-513-09-96: RD/CRLD/AN/9715286. Unpublished study prepared by Rhone-Poulenc Ag Company. 166 p.

44792007 Cousin, J. (1995) Phosalone Active Ingredients Octanol/Water Partition Coefficient: Lab Project Number: 94-161: RD/CRLD/AN/9515083. Unpublished study prepared by Rhone-Poulenc. 16 p.

44801001 Cousin, J. (1997) Phosalone Active Ingredient Water and Solvent Solubility: Lab Project Number: 97-09: RD/CRLD/AN/9718915. Unpublished study prepared by Rhone-Poulenc Agro. 25 p.

Case No. 0027
Chemical No. 097701

Case Name: Phosalone
Registrant: Rhone-Poulenc AG Company
Product(s): 94% TGAI

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	N/A ³	
830.1600	Description of materials used to produce the product	N ⁴	40901703
830.1620	Description of production process	Y	40901703, 44792005
830.1670	Discussion of formation of impurities	N ⁵	40901703, 40953401
830.1700	Preliminary analysis	Y	40953401, 44792005
830.1750	Certified limits	N/A ³	
830.1800	Enforcement analytical method	N/A ³	
830.6302	Color	Y	40901703
830.6303	Physical state	Y	40901703
830.6304	Odor	Y	40901703
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	40901703
830.6314	Oxidation/reduction: chemical incompatibility	N/A ³	
830.6315	Flammability	N/A ³	
830.6316	Explosibility	N/A ³	
830.6317	Storage stability	N/A ³	
830.6319	Miscibility	N/A ³	

830.6320	Corrosion characteristics	N/A ³	
830.7000	pH	Y	40901703
830.7050	UV/Visible absorption	N ⁶	
830.7100	Viscosity	N/A ³	
830.7200	Melting point/melting range	Y	40901703
830.7220	Boiling point/boiling range	N/A ⁷	
830.7300	Density/relative density/bulk density	Y	40901703
830.7370	Dissociation constants in water	N/A ⁸	
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	44792007
830.7840	Water solubility: column elution method; shake flask method	Y	44801001
830.7950	Vapor pressure	Y	40901703

¹ Y = Yes; N = No; N/A = Not Applicable.

² All references were reviewed under D260636.

³ Data are not required for the TGAI.

⁴ Rhone-Poulenc must either confirm that the sources of the starting materials have not changed with the change in the manufacturing facility or identify the source and specifications of the starting materials currently in use.

⁵ Rhone-Poulenc must provide additional discussion concerning the potential for formation of post-production impurities resulting from degradation of the ingredients in the product, migration of components of the packaging materials into the product, and carryover of contaminants from use of production equipment previously used to produce other products or substances.

⁶ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

⁷ Data are not required because the TGAI is a solid at room temperature.

⁸ Phosalone is not ionizable in water and is practically insoluble in water with no effect of pH on solubility between pH 4.5 and 10 (D260636).

PHOSALONE
PC Code 097701; Case No. 0027

Reregistration Eligibility Decision
Residue Chemistry Considerations

August 20, 1999

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

PHOSALONE

REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 097701; Case No. 0027

INTRODUCTION

Phosalone [*O,O*-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl] phosphorodithioate] is an organophosphate insecticide and acaricide for which U.S. registrations were voluntarily withdrawn in 1989 by the registrant, Rhône-Poulenc Ag Company (RPAC). The Agency proposed revoking tolerances for pesticides with no active registrations, including tolerances for residues of phosalone in/on plant and animal commodities (63 *FR* 3057, 1/21/98). However, in response to this proposal, RPAC requested that the Agency not revoke tolerances for phosalone residues in/on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and plums) so that these commodities could continue to be imported legally into the U.S. In the Final Rule published in the Federal Register of 10/26/98 (corrected 1/25/99), the Agency determined to maintain existing tolerances for residues of phosalone in/on the specified commodities while revoking the remaining phosalone tolerances under 40 CFR ' 180.263 and ' 186.4800.

REGULATORY BACKGROUND

Phosalone is a List A reregistration chemical and was the subject of a Registration Standard and Final Registration Standard and Tolerance Reassessment (FRSTR) dated 9/81 and 3/17/87, respectively. These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the FRSTR was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of phosalone.

The nature of phosalone residues in plants is adequately understood based on acceptable apple and grape metabolism studies. The Metabolism Assessment Review Committee (MARC) determined parent phosalone as the only residue of concern to be regulated in/on plant commodities (K. EL-Attar 10/04/99). Tolerances are currently established for residues of phosalone *per se* in/on almonds and almond hulls (0.1 and 50.0 ppm, respectively); apples, grapes and pears (10.0 ppm); and apricots, cherries, peaches, and plums (15.0 ppm) under 40 CFR

' 180.263. No tolerances are established for phosalone residues in processed plant commodities.

The Phosalone FRSTR (3/17/99) stated that ruminant feeding studies are available to support reregistration provided that the appropriate storage stability data on animal commodities are submitted. For the purposes of the reregistration of phosalone, given current foreign use patterns, the Branch determined the information on livestock metabolism and feeding studies to be adequate for the following reasons: (i) livestock feed items derived from crops for which import tolerances are being supported (almond hulls and wet apple pomace) are either not imported into the U.S. or are unlikely to be produced from imported fruit; (ii) countries in which phosalone residues are likely to occur in almond hulls and wet apple pomace, the exception being Canada, do not export significant amounts of livestock commodities to the U.S.; and (iii) the use of phosalone on apples in Canada is unlikely to result in a significant contribution of meat bearing phosalone residues relative to the total amount of beef available in the U.S. for consumption. However, if additional foreign uses of phosalone are registered which could lead to increased residues in livestock commodities exported to the U.S., a new ruminant metabolism study will be requested. No tolerance are currently established for animal products.

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

There are no registered domestic uses for phosalone on food/feed crops. There are three basic formulations of phosalone manufactured by RPAC that are registered for use on food/feed crops in countries that export treated commodities into the U.S. These include emulsifiable concentrate (350 g/L EC), flowable concentrate (500 g/L FLC), and wettable powder (30% WP) formulations marketed, primarily in Europe, under the trade names Zolone® and Rubitox®. Local formulations, which represent more dilute versions of the EC or WP products formulated with the same inerts, are also available in a few countries. These products may be applied as broadcast foliar applications using either ground or aerial equipment.

A summary of the registered food/feed use patterns of phosalone based on the product labels registered to RPAC in exporting countries, is presented in Table A (note: labels were provided by the registrant with translations as needed). A tabular summary of the residue chemistry science assessments for reregistration of phosalone is presented in Table B.

A review of the submitted labels and the available residue data indicates the following:

Almonds: The registrant has submitted data supporting the almond use pattern reflected by the French Good Agricultural Practices (GAP), which allows three applications of phosalone at 0.75 kg ai/ha/application totaling 2.25 kg ai/ha/season with a 70-day pre-harvest interval (PHI); this use pattern represents 1x the proposed European Union (EU) GAP rate.

Grapes: The registrant has submitted data supporting two applications of phosalone to grapes at 0.60 kg ai/ha/application totaling 1.20 kg ai/ha/season with a 21-day PHI. The French GAP allows an unspecified number of phosalone applications at a rate of 1.0 kg ai/ha/application with a 14-day PHI. The Canadian GAP permits three applications to grapes at 1.0 kg ai/ha/application for a total of 3.0 kg/ai/ha/season (2.5x the maximum rate applied in the grape field trials) with a 21-day PHI. Additional data are needed to support the French and Canadian use pattern. These labels are not supported by the available residue data.

Pome fruits: The registrant has submitted data supporting three applications of phosalone to pome fruits at 0.60 kg ai/ha/application totaling ~1.8 kg ai/ha/season (1x the proposed EU GAP rate) at nominal PHIs of 14, 21, and 28 days. The Canadian GAP allows a maximum use rate of 4.5 kg ai/ha/season, 2.5x the maximum rate; therefore, additional data are needed to support the Canadian use. In addition, the national GAPs for several countries do not specify the maximum number of applications allowed per season; although, most of these labels will be revised upon EU GAP harmonization. However, labels for non-EU countries need to specify the maximum number of applications allowed.

Stone fruits: The registrant has submitted data supporting two applications of phosalone to cherries at 0.60 kg ai/ha/application totaling 1.20 kg ai/ha/season with a 15-day PHI, and three applications of phosalone to peaches at 0.60 kg ai/ha/application totaling 1.8 kg ai/ha/season with a 28-day PHI (1x the proposed EU GAP rate). Several labels include the generic *Astone fruit* crop site or include apricots and plums. These labels are sufficient provided that the required plum data are submitted to support a tolerance for residues in/on the stone fruit crop group. In addition, the Canadian GAP for cherries and peaches allows a maximum use rate of 3.0 or 4.5 kg ai/ha/season, respectively, (2.5x the maximum EU rate); therefore, additional cherry and peach data are needed to support the Canadian use pattern. Several national GAPs do not reflect a maximum number of applications. Most of these labels will be revised upon EU GAP harmonization; however, labels for non-EU countries (Turkey, Czech Republic, and Slovak Republic) need to specify the maximum number of applications allowed.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on apple and grape metabolism studies. Tolerances for phosalone residues in/on plant commodities are currently expressed in terms of phosalone *per se*. Upon review of the plant metabolism data, the MARC determined parent phosalone as the only residue of concern to be regulated in/on plant commodities (K. EL-Attar 10/04/99).

The proposed metabolic degradation of phosalone in plants involves oxidation of the parent compound to the oxon analog (oxophosalone) and hydrolysis of the oxon to form 6-chlorobenzoxazolone. 6-Chlorobenzoxazolone, which may also arise directly from hydrolysis

of phosalone, is subsequently hydrolyzed to form 2-amino-5-chlorophenol, conjugated with sugars, or dehalogenated to form benzoxazolone. Phosalone is also dechlorinated to form deschlorophosalone, which yields benzoxazolone by hydrolysis. The chemical structures of phosalone and its metabolites in/on plant commodities are shown in Attachment 1.

In the apple metabolism study, total radioactive residues (TRR) were 18 and 27 ppm in/on whole fruit harvested 24 and 14 days, respectively, after a single application of [¹⁴C]phosalone at 3.4 kg ai/ha. Parent phosalone was the only residue identified and accounted for 77-81% of the TRR (13.96-21.71 ppm) in apple fruit; >95% of the calculated whole fruit TRR was associated with the peel.

Similar metabolism was observed in grapes. Total radioactive residues were 27-28 ppm in/on grapes harvested 23 days following a single application of [¹⁴C]phosalone at 2.1 kg ai/ha or 9 days following the second of two applications of [¹⁴C]phosalone at 1.05 kg ai/ha/application totaling 2.1 kg ai/ha. Greater than 95% of the TRR was in the pulp/skin (without juice), and parent phosalone was the major residue accounting for 90-102% of the TRR (24.9-27.5 ppm). The metabolites deschlorophosalone, oxophosalone, 6-chlorobenzoxazolone, benzoxazolone, and 2-amino-5-chlorophenol were each detected at ≤2% of the TRR.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

Metabolism data on poultry are not required as there are no poultry fed items derived from the imported crops for which phosalone uses are being supported. A livestock metabolism study was previously submitted but noted to be inadequate because of the insufficient characterization of radioactivity in tissues. The Chemistry Science Advisory Council (Chem SAC) has determined that animal metabolism information is required due to the potential, although small, for the importation of beef which might contain residues of phosalone. For the purposes of the reregistration of phosalone, given current foreign use patterns, the Branch considered the information in the available ruminant metabolism study to be adequate for the reasons discussed below. If additional foreign uses of phosalone are registered which could lead to increased residues in beef exported to the U.S., a new ruminant metabolism study will be required.

Only two livestock feed items are derived from crops for which import tolerances are being supported (almond hulls and wet apple pomace). Almond hulls are unlikely to be a significant source of phosalone residues for livestock commodities in the U.S. as hulls are not imported into the U.S. In addition, countries with registered uses for phosalone on almonds do not export significant quantities of livestock commodities to the U.S. With regards to wet apple pomace, the majority of apple imports are in the form of juice (84%), with 9% of apple imports being fresh fruit. It is unlikely that these imported apples will be used for processing; therefore, domestic livestock are unlikely to be fed wet apple pomace bearing phosalone residues. In addition, of the countries with registered uses of phosalone on apples, only Canada exports significant quantities of beef (3% of available commodity) to the U.S. If the percentage of the apple crop treated with phosalone in Canada (6.5%) is also considered, then only 0.2% of the available beef supply could

possibly contain phosalone residues.

Furthermore, the Phosalone FRSTR (3/17/87) stated that cow feeding studies were available to support reregistration, provided that the appropriate storage stability data on animals are submitted by the registrant. Considering current highest average field trial (HAFT) residues of 1.53 ppm in/on apples and ~2x concentration factor for wet apple pomace (Phosalone Registration Standard 9/81), phosalone residues of 3.06 ppm are maximumly expected in wet apple pomace. The feeding study conducted at 100, 200, and 500 ppm (33, 66, 166 x the residue levels maximumly expected in wet apple pomace, respectively) showed phosalone residues of 0.01-0.023 ppm in fat, 0.057-0.074 ppm in liver, and non-detectable residues in muscle and kidney at the 100 ppm dose level. Data on milk from an earlier study conducted at up to 100 ppm indicated non-detectable residues. These data suggest finite residues of phosalone are unlikely in beef commodities at the 10x feeding level [40 CFR 180.6 (a)(3)]. However, livestock metabolism studies may be required if additional uses for phosalone are proposed by the registrant in the future.

OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of phosalone residues in/on plant commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a GC/electron capture detection (ECD) method (Method I) for determining residues of phosalone *per se* in/on plant commodities together with a confirmatory TLC method (Method A). PAM Vol. II also includes a citation for a GC method (Method B) published in *J.A.O.A.C.* that detects various organophosphates (OPs) by potassium chloride thermionic detector.

Data submitted recently to support phosalone tolerances in/on imported almonds, grapes, pome and stone fruit were collected using GC/nitrogen-phosphorus detection (NPD) or flame photometric detection (FPD) method AR 148-97, or slight modification thereof, which is similar to the available tolerance enforcement method published in the PAM Vol. II.

Briefly, residues of phosalone are extracted from crop matrices with acetone:water (80:20, v/v), filtered, and concentrated. The residues are diluted with water and a saturated solution of sodium sulfate, partitioned into dichloromethane, filtered over sodium sulfate, and concentrated to dryness. The residues are then redissolved in toluene and analyzed by GC/NPD or FPD. The validated LOQ (limit of quantitation) is 0.05 ppm for residues of phosalone in/on plant commodities.

Methodology for determining phosalone in animal tissues is not required since tolerance are not being supported for phosalone residues in animal commodities under the current submission.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database (PAM Vol. I, Appendix I, dated 1/94) indicates that phosalone is completely recovered (>80%) by Multiresidue Methods Section 302 (Section 232.4; Protocol D), 303 (Section 211.1; Protocol E, fatty), and 304 (Section 212.1; Protocol E, fatty).

OPPTS GLN 860.1380: Storage Stability Data

The requirements for storage stability data are satisfied for all acceptable residue studies on plant commodities. Recently submitted data indicate that residues of phosalone are stable at approximately -18 C in almonds, apples, cherries, and peaches for at least 19-24 months. Furthermore, the Phosalone FRSTR (3/17/87) stated that phosalone residues are stable in frozen plant matrices for up to 3 years.

Storage stability data for phosalone in animal tissues is not required since tolerances are not being supported by the registrant for phosalone residues in animal commodities according to the present petition.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

The requirements for magnitude of the residue data in/on plants are fulfilled for almonds. Adequate field trial data depicting phosalone residues of phosalone *per se* in/on almond nutmeat following applications made according to the maximum use pattern were submitted by the registrant. Geographical representation is adequate and a sufficient number of trials were conducted in the study. Although the label for the Italian 500 g/L FIC formulation specifies a 21-day PHI for almonds under use directions for drupes, almond residue data supporting a 21-day PHI on almonds in Italy are not required as Italy does not export significant quantities of almonds to the U.S. In addition, data on almonds hulls are not needed since hulls are not imported by the U.S. The field trials showed phosalone residues of <0.05-0.07 ppm in/on six samples of almond nutmeat harvested 78 days following three applications of phosalone at 0.77 kg ai/ha/application totaling 2.3 kg ai/ha/season (1x the proposed EU GAP).

The submitted data on grapes are not adequate to support reregistration because an insufficient number of tests were conducted at the maximum rate. Data reflective of the French and Canadian GAP are required depicting residues of phosalone *per se* in/on grapes. A total of four additional tests are required on grapes--two conducted at 1x the French GAP and two conducted at 1x the Canadian GAP. The tests should be performed at appropriate locations in France and Canada/U.S. The available data are from two tests on grapes performed in Italy at 1x the proposed European GAP. Residues of phosalone *per se* were 0.22 and 0.53 ppm in/on two treated grape samples harvested 21 days after two foliar applications of phosalone at 0.60 kg ai/ha/application totaling 1.2 kg ai/ha/season.

The submitted residue data on pome fruits are not adequate to support reregistration because the geographic distribution of the tests and the number of tests reflecting the maximum use rate are insufficient. No pome fruit studies were conducted in Canada, which accounts for 5% of the apple commodities imported into the U.S. and which allows the highest maximum seasonal rate among countries with uses registered on pome fruits. Data are required depicting residues of phosalone *per se* in/on pome fruits harvested 30 days after the last of three foliar applications at 1.5 kg ai/ha/application (4.5 kg ai/ha/season; 1x the Canadian GAP). An additional five trials on apples (3 tests) and pears (2 tests) performed at appropriate locations in Canada and/or the U.S. at 1x the Canadian GAP are required to support tolerances for residues of phosalone in/on imported pome fruits.

The available data on apples and pears are from tests performed in Europe and Japan at 1x the proposed rates for these countries. Residues of phosalone *per se* were 0.38-1.12 ppm in/on 13 samples of apples and pears harvested 14-16 days after three applications of phosalone totaling 1.8-2.8 kg ai/ha (1-1.5x the French and Spanish GAP rate); 0.36-1.24 ppm in/on 18 samples of apples and pears harvested 18-24 days after three treatments totaling 1.8-2.7 kg ai/ha (1-1.5x the Italian GAP); and 0.23-1.54 ppm in/on 23 samples of apples and pears harvested 27-31 days following 3-4 applications of phosalone totaling 1.8-3.0 kg ai/ha/season (1-1.7x the proposed EU GAP). In addition, residues were 0.10-0.82 ppm in/on 12 apple and pear samples harvested 43 or 45 days after 2-3 applications of phosalone totaling 0.35 or 0.53 kg ai/ha/season (1-1.5x the Japanese GAP).

The submitted residue data on stone fruits are not adequate to support reregistration because the geographic distribution of the tests on cherries and the number of tests reflecting the maximum use rates for stone fruits are insufficient. No tests were conducted on cherries in Canada, a country supplying 7% of the cherries imported into the U.S., and no tests were performed at the maximum use rates for cherries and peaches specified by the Canadian GAP. In addition, no studies were conducted at any location on plums, a representative crop for the stone fruits crop group. Data are required depicting residues of phosalone *per se* in/on cherries harvested 14 days after the last of two foliar applications to cherries at 1.5 kg ai/ha/application (3.0 kg ai/ha/season; 1x the Canadian GAP). Data are also required depicting residues of phosalone *per se* in/on peaches and plums harvested 30 days after the last of three foliar applications at 1.5 kg ai/ha/application (4.5 kg ai/ha/season; 1x the Canadian GAP). An additional three trials each on cherries, peaches, and plums (a total of 9 tests) performed at appropriate locations in Canada and/or the U.S. at 1x the Canadian GAP are required to support tolerances for residues of phosalone in/on imported stone fruits.

The available data on stone fruits are from tests on cherries and peaches performed in Europe at 1x the proposed European rates. Following two foliar applications of phosalone at 0.60 kg ai/ha/application totaling ~1.2 kg ai/ha/season (1x the French GAP), residues of phosalone *per se* were 0.32-0.78 ppm in/on whole cherries 8-11 days post-treatment (n=12), 0.15-0.72 ppm 14-17 days post-treatment (n=14), and 0.08-0.43 ppm (n=16) 18-26 days post-treatment. Phosalone

residues were 0.29-0.89 ppm in/on seven peach samples harvested 26-29 days after three applications of phosalone at 0.60-0.90 kg ai/ha/application totaling 1.8-2.7 kg ai/ha/season (1-1.5x the proposed EU GAP rate). (1-

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apples, grapes, and plums.

Phosalone residues concentrate by ~2x in raisins according to the Phosalone Registration Standard 9/81. Data are not available depicting residues in grape juice; however, concentration of phosalone residues in grape juice is not probable as the grape metabolism study shows that phosalone residues are low in grape juice (1.4% TRR) in relation to the levels found in grape pulp including skin (86.6% TRR). No tolerances for residues in processed grape commodities are required at this time. The current HAFT residues of 0.375 ppm in/on grapes and the 2x concentration factor for raisins indicate that residues of 0.8 ppm might be expected in raisins.

The registrant submitted data depicting residues of phosalone in apple commodities processed from apples bearing measurable residues. Phosalone (500 g/L EC) was applied four times foliarly to apples at 0.60 kg ai/ha/application at 13-15 day retreatment intervals for a total of 2.4 kg ai/ha/season (1.3x the French GAP rate). One control, two treated samples (2 kg), and one bulk treated sample (330 kg) of apple fruit were harvested 15 days following the last application of phosalone. The apples were shipped and processed into apple fractions using simulated commercial practice for producing baby food, and frozen within one month of collection. Processed fractions were obtained after peeling and cooking, and included refined pulp and compote (i.e. apple sauce); apple pomace and apple juice samples were not collected during the study. The processed samples were analyzed for phosalone using Method CNG-AN 4432 (modified to be essentially the same as the adequate GC/NPD method, Method AR 148-97). The analysis indicated a reduction factor of 0.3x for the refined pulp and compote/sauce of the unwashed, peeled fruit, and the refined pulp and compote/sauce of the washed, unpeeled fruit.

The submitted apple processing study did not provide data on residues of phosalone in apple juice or wet pomace. However, the results of the apple metabolism study show that phosalone residues are low in apple pulp in relation to parent content in the peel; residues, therefore, are not likely to concentrate in juice. Current HAFT residues of 1.53 ppm in/on apples and a ~2x concentration factor for wet pomace (noted in the Phosalone Registration Standard 9/81) indicate that phosalone residues of 3.06 ppm are maximumly expected in wet apple pomace. As it is unlikely that imported apples will be processed into wet pomace and fed to livestock, and that phosalone residues do not concentrate in juice, tolerances for residues in/on processed apple commodities are not required at this time.

The available plum processing studies noted in the Phosalone Registration Standard 9/81 indicate that phosalone residues concentrate by a maximum of ~2.5x in prunes. Field trial data depicting residues of phosalone in/on plums are needed to determine the level of phosalone residues expected in prunes. Imported prunes account for ~2% of the prunes available for consumption in the U.S.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The Phosalone FRSTR (3/17/87) stated that adequate ruminant feeding studies are available to support reregistration provided that the appropriate storage stability data on animal commodities are submitted. New livestock metabolism/feeding studies and tolerances for residues of phosalone in animal commodities are not required at this time because (i) livestock feed items derived from crops for which import tolerances are being supported (almond hulls and wet apple pomace) are either not imported into the U.S. or are not likely to be produced from imported fruit; (ii) with the exception of Canada, countries in which phosalone residues are likely to occur in almond hulls and wet apple pomace do not export significant amounts of livestock commodities to the U.S.; and (iii) the use of phosalone on apples in Canada is unlikely to result in a significant contribution of meat bearing phosalone residue to the total amount of beef available in the U.S. for consumption.

The results of the 28-day cattle feeding study reviewed in the Phosalone FRSTR are summarized in the table shown below. The data from the feeding study indicate that finite residues of phosalone might be expected to occur in beef liver and fat at a 100 ppm feeding level, but not in muscle, kidney, or milk.

Residues of phosalone in the tissue and milk of dairy cattle dosed with phosalone in the diet for 28 days ^a

Matrix	Dosing Level		
	100 ppm	200 ppm	500 ppm
	Phosalone (ppm)		
Liver	0.057, 0.074	0.025, 0.095	0.035, 0.179
Muscle	NA ^b	NA ^b	<0.01-0.020
Kidney	NA ^b	<0.01	0.013, 0.016
Fat	0.010, 0.023	0.038, 0.068	0.070, 0.139
Milk ^a	<0.025	--	--

^a Data on milk are from an earlier study in which dairy cows were fed phosalone at up to 100 ppm in the diet for 37-39 days (reported in the Phosalone Registration Standard, dated 9/81).

^b NA = Not analyzed.

[note: USDA-FSIS monitoring data (DP Barcode D246819, S. Hummel, 6/2/98) for chlorinated organophosphates for 1993-1997 detected no finite residues (<0.02 ppm) of phosalone in fat of cattle, goats, horses, hogs, sheep, and poultry (n=138-2577 for various species)].

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

Phosalone is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-handling Establishments

Phosalone is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

As almonds, grapes, pome and stone fruits are perennial crops, confined and field rotational crop studies are not required for reregistration.

Table A. Food/Feed Use Patterns Subject To Reregistration for Phosalone (Case 0027).

Country	Crop	Formulation	Application Parameters			PHI ^a (days)
			Rate/appl. (kg ai/ha)	Spray Concentration (kg ai/hl)	Number of applications	
Almonds						
France ^b	Almond	350 g/L EC	0.75	--	3	70
France	Almond	500 g/L FIC	0.75	--	3	70
Italy	Stone fruit (Almond)	350 g/L EC	0.5-0.7 ^c	0.05-0.07	NS ^d	21
Grapes						
Canada ^e	grapes	500 g/L FIC	1.0	--	3	21
Italy	vines	350 g/L EC	0.5-0.7 ^c	0.05-0.07	NS	21
France ^f	vines		1.0	0.06	NS	14
France ^f	vines	500 g/L FIC	1.0	0.06	NS	14
Portugal	vines	300 g/kg WP	0.6 ^c	0.06	NS	21
Spain	vines		0.7 ^c	0.07	NS	15
Fruit Trees (unspecified)						
Austria ^g	Fruit trees	350 g/L EC	0.5-0.7 ^c	0.05-0.07	NS	21
Croatia	Fruit trees		0.7-0.9 ^c	0.07-0.087	3	35
Greece ^g	Fruit trees		0.5-0.7 ^c	0.05-0.07	NS	21
Hungary ^g	Fruit trees		0.61	--	NS	21
Hungary ^g	Orchard crops	300 g/kg WP	0.6 ^c	0.06	NS	NS
Poland ^g	Fruit trees	350 g/L EC	0.63-0.91	--	NS	15
Spain ^g	Fruit trees	300 g/kg WP	0.7 ^c	0.07	NS	15
Pome fruits						
Belgium ^g	Apple, pear	500 g/L FIC	0.5-0.75	--	NS ⁱ	28
Canada	Apple, pear		1.0-1.5	--	3	30
Czech Republic	Pome Fruit	350 g/L EC	0.7 ^c	0.07	NS	21
European Union ^j	Apple, pear		0.6 ^c	0.06	3	28
European Union ^j	Apple, pear	300 g/kg WP	0.6 ^c	0.06	3	28
France	Apple, pear	350 g/L EC	0.6 ^c	0.06	NS	14
France	Apple, pear	500 g/L FIC	0.6 ^c	0.06	NS	15
Italy	Apple, pear	350 g/L EC	0.5-0.7 ^c	0.05-0.07	NS	21
Portugal	Apple, pear	300 g/kg WP	0.6 ^c	0.06	NS	21
Japan	Apple, pear	350 g/L EC	0.2-0.4 ^c	0.023-0.035	2	45
Russia	Apple, pear		0.7-1.4	--	2	30 south 40 north
Slovak Republic	Pome fruit		0.7 ^c	0.07	NS	21
Switzerland	Pome fruit		0.79-1.05	--	NS	30

Country	Crop	Formulation	Application Parameters			PHI ^a (days)
			Rate/appl. (kg ai/ha)	Spray Concentration (kg ai/hl)	Number of applications	
Turkey	Apple		0.7 ^c	0.07	NS	15

Country	Crop	Formulation	Application Parameters			PHI ^a (days)
			Rate/appl. (kg ai/ha)	Spray Concentration (kg ai/hl)	Number of applications	
Stone fruits						
Canada ^e	Cherry	500 g/L FIC	1.0-1.5	--	2	14
	Peach, Plum				3	30
Czech Republic	Stone fruit	350 g/L EC	0.7 ^c	0.07	NS	21
European Union ^j	Stone fruit		0.6 ^c	0.06	Cherry 2 Others 3	15 28
European Union	Stone fruit	300 g/L EC	0.6 ^c	0.06	Cherry 2 Others 3	15 28
France ^k	Apricot, Peach	350 g/L EC	0.6 ^c	0.06	NS	14
France ^k	Apricot	500 g/L EC	0.6 ^c	0.06	NS	15
France ^k	Cherry	350 g/L EC	0.60	--	2	14
France ^k	Cherry	500 g/L FIC	0.60	--	2	14
France ^k	Peach		0.6 ^c	0.06	NS	15
France ^k	Plum	350 g/L EC	0.6-0.7 ^c	0.06-0.07	NS	14
France	Plum	500 g/L FIC	0.6-0.7 ^c	0.06-0.07	NS	15
Italy ^k	Stone fruit	350 g/L EC	0.5-0.7 ^c	0.05-0.07	NS	21
Portugal	Plum, Apricot, Peach	300g/kg WP	0.6 ^c	0.06	NS	21
Russia	Apricot	350 g/L EC	0.7-0.84	--	1	45
Russia	Cherry; Plum		0.28-0.98	--	2	40
Russia	Peach		0.56-0.84	--	1-2 ¹	30-40 ¹
Slovak Republic	Stone fruit		0.7 ^c	0.07	NS	21
Switzerland	Stone fruit		0.79-1.05	--	NS	30
Turkey	Cherry		0.6 ^c	0.06	NS	15
Turkey	Plum		0.7 ^c	0.07	NS	15

^a Pre-harvest Interval.

^b Pending approval by authorities. This use pattern will also be the proposed as the GAP for the EU on almonds.

^c Rate (kg ai/ha) not specified; rate indicated is based on the stated target spray volume of 1000 liters water/ha.

^d NS = Not specified.

^e Pending approval by authorities.

^f Phosalone is no longer marketed on grapes in France and the use will be removed from the label.

^g According to the registrant, currently registered national labels will be revised to reflect the EU GAP (three applications at 0.6 kg/ai/ha/application with a 28-day PHI).

^h According to the registrant, currently registered national labels will be revised to reflect the EU GAP.

ⁱ Used in IPM programs, rarely exceeding two applications.

^j Reflects the proposed EU GAP.

^k According to the registrant, currently registered national labels will be revised to reflect the EU GAP.

^l One application (35 day-PHI) and two applications (40-day PHI) for mid- and late-season varieties, respectively.

Table B. Residue Chemistry Science Assessments for Reregistration of Phosalone.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A	Yes ²	See Table A.
860.1300: Plant Metabolism	N/A	No	00062878 00062879 44792018 ³ 44792019 ³
860.1300: Animal Metabolism	N/A	No ⁴	00064523
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00062880 00064634 00086695 00109468 00144442 00159274 05003635 05007744 05007745 05008190 05009309 05014688 05016356 44792020 ³ 44792021 ³
- Animal commodities	N/A	No ⁵	00064522 00064524 00064525 00064528 00064530
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	No	00062881 44792022 ³
860.1500: Crop Field Trials			
<u>Pome Fruits Group</u>			
- Apples	10.0 [§180.263]	Yes ⁶	44792023 ³ 44792024 ³ 44792025 ³ 44792026 ³ 44792027 ³ 44792028 ³ 44792030 ³ 44792031 ³ 44792032 ³ 44792024 ³
- Pears	10.0 [§180.263]	Yes ⁶	44792029 ³ 44792033 ³
<u>Stone Fruits Group</u>			
- Apricots	15.0 [§180.263]	No ⁷	
- Cherries	15.0 [§180.263]	Yes ⁷	44792035 ³ 44792037 ³
- Peaches	15.0 [§180.263]	Yes ⁷	44792036 ³ 44792038 ³ 44792039 ³ 44792040 ³
- Plums (Fresh Prunes)	15.0 [§180.263]	Yes ⁷	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>Tree Nuts Group</u>			
- Almonds	0.01 [180.263]	No	44792041 ³ 44792042 ³ 44792043 ³ 44792044 ³ 44792045 ³
- Almond, hulls	50.0 [§180.263]	No ⁸	
<u>Miscellaneous Crops</u>			
- Grapes	10.0 [180.263]	Yes ⁹	44792034 ³
860.1520: Processed Food/Feed			
- Apple	None	No ¹⁰	00006068 00006357
- Grapes	None	No ¹¹	00006480
- Plums	None	No ¹²	00006769 00006487
860.1480: Meat, Milk, Poultry, and Eggs			
- Meat, Meat-by-products, and fat of cattle, goats, hogs, horses, and sheep	None	No ⁴	00064524
- Milk	None	No ⁴	00064524
- Meat and Meat-by-products of poultry	None	No ⁴	
- Eggs	None	No ⁴	
860.1400: Water, Fish, and Irrigated Crops	None	N/A	
860.1460: Food Handling	None	N/A	
860.1850: Confined Rotational Crops	N/A	N/A	
860.1900: Field Rotational Crops	None	N/A	

1. **Bolded** references were cited in the Phosalone Registration Standard (9/81); all others were reviewed or summarized in the Phosalone FRSTR, dated 3/17/87, unless otherwise noted.
2. Summaries of the supported use directions are presented in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use.
3. DP Barcode D260637, K. EL-Attar 11/01/99.
4. HED has determined that livestock metabolism and feeding studies are not required at this time. Of the two feed items derived from crops for which import tolerances are being supported, almond hulls and wet

apple pomace, only apple pomace could potentially be used as livestock feed in the U.S. It is unlikely that the relatively small amount of imported fresh apples would be processed into wet pomace and fed to livestock. In addition, there are either not significant imports of livestock commodities from countries with registered uses of phosalone on almonds and apples, or as in the case with Canada, the amount of exported beef potentially bearing phosalone residues is unlikely to contribute significantly to the total amount of beef available in the U.S.

5. Methodology for determining phosalone in animal tissues is not required since tolerances are not being supported for phosalone residues in animal commodities at this time.
6. Data are required depicting residues of phosalone *per se* in/on pome fruits harvested 30 days after the last of three foliar applications at 1.5 kg ai/ha/application (4.5 kg ai/ha/season; 1x the Canadian GAP). An additional five trials on apples (3 tests) and pears (2 tests) performed at locations in Canada and/or the U.S. at 1x the Canadian GAP are required to support tolerances for residues of phosalone in/on imported pome fruits.
7. Data are required depicting residues of phosalone *per se* in/on cherries harvested 14 days after the last of two foliar applications to cherries at 1.5 kg ai/ha/application (3.0 kg ai/ha/season; 1x the Canadian GAP). Data on are also required depicting residues of phosalone *per se* in/on peaches and plums harvested 30 days after the last of three foliar applications at 1.5 kg ai/ha/application (4.5 kg ai/ha/season; 1x the Canadian GAP). An additional three trials each on cherries, peaches, and plums (a total of 9 tests) performed at appropriate locations in Canada and/or the U.S. at 1x the Canadian GAP are required to support tolerances for residues of phosalone in/on imported stone fruits.
8. Data on almonds hulls are not needed as the Agency has determined that a tolerance for residues in/on imported almond hulls is not required.
9. Data are required from an additional four tests depicting residues of phosalone *per se* in/on grapes—two conducted at 1x the French GAP and two conducted at 1x the Canadian GAP. The tests should be performed at appropriate locations in France and Canada/U.S.
10. As it is unlikely that imported apples will be processed into wet pomace and fed to livestock, and phosalone residues do not concentrate in juice, tolerances for residues in/on imported processed apple commodities are not required at this time.
11. Phosalone residues are not expected to concentrate in juice, but concentrate by ~2x in raisins. The current HAFT residues of 0.375 ppm in/on grapes and the 2x concentration factor for raisins indicate that residues of 0.8 ppm might be expected in raisins. Additional residue data on grapes are needed to determine the magnitude of a tolerance for imported raisins.
12. The available plum processing studies indicate that phosalone residues concentrate by a maximum of ~2.5x in prunes. Residue data depicting residues of phosalone in/on plums are needed to determine the magnitude of a tolerance for residues in prunes.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for phosalone residues are currently expressed in terms of phosalone *per se* in or on plant commodities [40 CFR §180.263]. The MARC determined parent phosalone as the only residue of concern to be regulated in/on plants. There are currently no tolerances for residues of phosalone in animal commodities. A summary of the phosalone tolerance reassessment for crop commodities and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.263:

Sufficient data are available to reassess the tolerance for phosalone residues in/on almond nutmeat. Based upon the currently proposed use pattern and the available residue data, the established tolerance of 0.1 ppm is adequate for phosalone residues in/on almond nutmeat. The established tolerance for phosalone residues in/on almond hulls (50.0 ppm) should be revoked as the Agency has previously determined that a tolerance for residues in/on imported almond hulls is not required; almond hulls are not imported.

Additional data are required on grapes, apples, pears, plums, peaches, and cherries before the tolerances for residues in/on these commodities can be reassessed. The available data indicate that the established tolerances (10.0 ppm for apples, grapes and pears; 15.0 ppm for apricots, cherries, peaches, and plums) are too high. Based upon the available residue data, tolerances for residues may be lowered to 1.0 ppm for grapes and stone fruits, and 2.0 ppm for pome fruits. However, additional data reflecting the slightly higher use rate of the Canadian GAP are required before the tolerance can be reassessed.

There are currently no tolerances for residues of phosalone in animal commodities and the Agency has determined that none are required to support the proposed uses in/on imported commodities.

Tolerances Needed Under 40 CFR §180.263:

Tolerances are needed for phosalone residues in/on raisins and prunes. However, before the magnitude of phosalone tolerances can be assessed, additional data are required depicting phosalone residues in grape and plums.

In addition, the available data on apples, pears, cherries, and peaches suggest that crop group tolerances may be appropriate for the pome and stone fruit crop groups. If phosalone residues in/on apples, pears, peaches, cherries, and plums from the requested Canadian studies are similar to the available data from Europe and Japan for these commodities, then crop groups should be established for pome fruits and stone fruits and the separate tolerances for the members of these groups should be revoked.

Table C. Tolerance Reassessment Summary for Phosalone.

Table C: Tolerance Reassessment Summary for Phosalone			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.263:			
Almonds	0.1	0.1	<i>Almond, nutmeat</i>
Almonds, hulls	50.0	Revoke	Almond hulls are not imported.
Apples	10.0	TBD ^a	The available data indicate that the established tolerances are too high and may be lowered to 1.0 ppm for residues in/on grapes and stone fruits, and 2.0 ppm for residues in/on pome fruits. However, additional data reflecting the slightly higher use rate of the Canadian GAP are required before the tolerances can be reassessed.
Apricots	15.0		
Cherries	15.0		
Grapes	10.0		
Peaches	15.0		
Pears	10.0		
Plums (fresh prunes)	15.0		
Tolerances needed under 40 CFR §180.263			
Raisins	None	TBD	Additional data on grapes are needed to assess an appropriate tolerance for residues in raisins.
Prunes	None	TBD	To assess an appropriate tolerance for residues in prunes, data are needed from field trials on plums. Phosalone residues concentrate by ~2x in prunes.
Pome fruits	None	TBD	The available residue data on imported apples, pears, peaches, and cherries suggest that crop group tolerances may be appropriate for pome and stone fruits. If the requested residue data on pome and stone fruits from Canadian studies are similar to the available data from Europe and Japan, then crop groups should be established for pome fruits and stone fruits concomitant with revoking the individual tolerances for the members of these crop groups.
Stone fruits	None	TBD	

^a TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

DIETARY EXPOSURE ASSESSMENT SUMMARY

For reregistration and risk assessment purposes, adequate plant metabolism data are available. In addition, new animal metabolism and feeding studies are not required to support the uses on imported almonds and fruits. However, magnitude of the residue data for phosalone residues are required for all registered uses the registrant is supporting, with the exception of almonds. The available residue data on grapes, pome fruits, and stone fruits indicate that the established tolerances for these commodities are too high. However, additional data reflecting the slightly higher use rate of the French GAP on grapes and the Canadian GAP on grapes, apples, pears, cherries, and peaches are required before the tolerance can be reassessed. As residue data from the country with the highest use rates is outstanding (Canada), tolerance reassessment and risk assessment cannot be conducted at this time. Adequate residue data are available for all processed commodities.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for phosalone in/on various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues*); there are no MRLs for animal commodities. Codex MRLs for phosalone are currently expressed in terms of the parent for plant commodities. Additional U.S. residue data for apples and grapes are required to before a decision can be made on harmonizing U.S. tolerances for these crops with the Codex MRLs. A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for phosalone and applicable U.S. tolerances.

Codex			U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL ^a (mg/kg)	Step		
Apple	5.0	CXL	10.0	Additional residue data are required.
Citrus fruit	1.0	CXL	None	Not considered in terms of present petition
Grapes	5.0	CXL	10.0	Additional residue data are required.
Potato	0.1 (*) ^b	CXL	None	Not considered in terms of present petition

^a JMPR 1994 recommended withdrawal for all Codex MRLs for phosalone. As new supervised trial data will become available in 1999, the Committee decided to maintain the CXL for 4 years according to the periodic review procedure.

^b Asterisk designates MRL set at or about the limit of determination.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: D255208

Subject: Phosalone (PC Code: 097701; DP Barcode D255208). Decision Memorandum for 09/21/99 meeting of Metabolism Assessment Review Committee regarding the proposal for parent phosalone as the only residue of concern based on apple and grape metabolism studies.

From: K. EL-Attar

To: Files

Dated: 10/04/99

MRID(s): None

DP Barcode: D246819

Subject: Summary of USDA-FSIS Monitoring Data for Chlorinated Organophosphates from 1993 through 1997: carbophenothion (Trithion, 058102), chlorpyrifos (059101), chlorfenvinphos (084101), coumaphos (036501), coumaphos oxon (), dichlorvos (DDVP, 084001), ethion (58401), phosalone (097701), ronnel (058301), tetrachlorvinphos (Gardona, or stirophos, 083701), and trichlorfon (057901).

From: S. Hummel

To: Files

Dated: 6/2/98

MRID(s): None

RESIDUE CHEMISTRY CITATIONS

00006068 Guardigli, A. (1972) Phosalone Transfer in Fruits Processing: Possible Residue in Raw Apple Juice and Dry Apple Pomace: Laboratory Experiments. (Unpublished study received Feb 16, 1972 under 2H5013; submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:221747-C)

00006357 Rhodia, Incorporated (1972?) Phosalone Dried Apple Pomace Data. Includes undated method. (Unpublished study received Jun 26, 1972 under 0F0983; prepared in cooperation with Cornell Univ., New York State Agricultural Experiment Station, Dept. of Food Science and Technology; CDL:091691-A)

00006480 Guardigli, A.; Martwinski, P. (1971) Residue Data: [Zolone]. (Unpublished study including field test project nos. BB 65-63, BB 68-91, PA 68-46, PA 70-25/25A, PA 70-26, PA 70-27/27A and PAW 70-29, received Nov 18, 1971 under 359-626; prepared by Rhodia, Inc., submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:003175-X)

00006487 Henckler, P.M.; Rice, R. (1973) Residue Summary: Plums: Project No. 180473-033. (Unpublished study received Mar 29, 1974 under 359-620; prepared by Rhodia, Inc. in cooperation with Univ. of California, submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:028124-G)

00006769 Guardigli, A. (1964) Laboratory Analytical Data Sheet for Residues: Field Test Project No. BB 64-26. (Unpublished study received Feb 2, 1967 under 7G0575; prepared by Rhodia, Inc., submitted by Chipman Chemical Co., Inc., Burlingame, Calif.; CDL:090727-L)

00062878 Hutsell, T.C.; Mulkey, N.S.; Wargo, J.P., Jr.; et al. (1978) Research Report: 14 C-Phosalone Sorghum Metabolism Study: ADC Project No. 299. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099782-A)

00062879 Penner, D. (1977) Sorghum Metabolism Study with 14 C-Phosalone: Report on: I. Growing, Treatment, and Harvest of the Sorghum; II. 14 C-Phosalone Translocation Study. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Michigan State Univ., Dept. of Crop and Soil Sciences, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099782-B)

00062880 Wargo, J.P., Jr.; Tessier, J.F.; Kruplak, J.F.; et al. (1980) Validation of Methods 54A and 144 for the Determination of Phosalone and Metabolites in Raw Agricultural Commodities: ADC Project # 460. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099782-C)

00062881 Rhone-Poulenc Chemical Company (1978) Freezer Storage Stability Test on Alfalfa. (Unpublished study received Dec 4, 1980 under 359-620; CDL:099782-D)

00064522 Buys, M.; Guardigli, A. (1980) Validated Enforcement Methodology for Animal Substrates: PDD Report No. 80/016. Method no. 155 dated Oct 1980. (Unpublished study received Dec 4, 1980 under 359-620; prepared in cooperation with Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099784-A)

00064523 Witkonton, S. (1980) Research Report: Validation of Analytical Methods for the Determination of Phosalone and Its Metabolites in Milk and Animal Tissues: ADC Project # 496. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099784-B)

00064524 Craig, L.D.; Langknecht, J.C.; Adams, L.; et al. (1980) Research Report: Residue Determination of Phosalone and Its Oxygen Analog in the Milk and Tissues of Dairy Cattle by Electron Capture Gas Chromatography: ADC Project # 475-D. Includes method dated May 16, 1980. (Unpublished study, including ADC project #s 475-A&B and 475-C, received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical

00064525 Fox, S.E.; Langknecht, J.C.; Busemeyer, F.; et al. (1980) Research Report: Residue Determination of Phosalone and Its Oxyon Analog in the Eggs and Tissues of Chickens: ADC Project # 507. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099785-B)

00064528 Fox, S.E.; Herrera, R. (1980) Research Report: Residue Determination of Metabolites Containing the Chlorobenzoxazole Moiety in Tissues and Eggs from Laying Hens Fed Phosalone: ADC Project # 507-A. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099785-E)

00064530 Breault, G.O.; Fox, S.E. (1980) Confirmation of Phosalone in Chicken Tissues by Gas Chromatography/Mass Spectrometry. (Unpublished study received Dec 4, 1980 under 359-620; prepared by Analytical Development Corp., submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:099785-G)

44792018 Toia, R.; Kimmel, E.; Periasamy, R. (1995) A Metabolism Study with (carbon-14)-Phosalone on Grapes: Lab Project Number: 385W-1: 358W: EC-92-218. Unpublished study prepared by PTRL West, Inc. 309 p.

44792019 Ewing, A.; Kimmel, E.; Ruzo, L. (1999) A Metabolism Study with (carbon-14)-

Phosalone on Apples (*Pyrus malus*): Final Report: Lab Project Number: 181-W: 181W.
Unpublished study prepared by PTRL West, Inc. 89 p.

44792020 Gabereau, M. (1997) Phosalone: Analytical Method for the Determination of Residues in Plants: Lab Project Number: AR 148-97: 97-95-18: 97-95. Unpublished study prepared by Rhone-Poulenc. 40 p. {OPPT 860.1340}

44792021 Yslan, F.; Bourgade, C. (1998) Phosalone: Confirmatory Method for the Determination of Residues in Plants: Lab Project Number: 97-189: RD/CRLD/AN/9815432: AR 159-97. Unpublished study prepared by Rhone-Poulenc. 25 p. {OPPTS 860.1340}

44792022 Quintelas, G. (1998) Stability Study of Phosalone in Fruits after Storage in a Freezer at a Temperature Near-18 degrees Celsius: Lab Project Number: 98-162: RPA/98-072. Unpublished study prepared by Rhone-Poulenc. 26 p. {OPPTS 860.1380}

44792023 Muller, M. (1999) Phosalone: Formulation: Zolone 25L (EC) Test in Italy, 1989 Residues in Apples: Final Report: Lab Project Number: 89556: AG/CRLD/AN/8916827. Unpublished study prepared by Rhone-Poulenc. 23 p. {OPPTS 860.1500}

44792024 Muller, M. (1999) Phosalone: Formulation: Zolone 25L (EC) Tests in Italy, 1989 Residues in Leaves and Fruit of Apples: Lab Project Number: AG/CRLD/AN/9015907. Unpublished study prepared by Rhone-Poulenc. 21 p. {OPPTS 860.1500}

44792025 Maestracci, M. (1997) Phosalone: Formulation EXP05531D (EC) Trial France 1996 Residues in Apple Decline Study (Reverse Curve): Lab Project Number: 96-775: RD/CRLD/ANDBE9716155. Unpublished study prepared by Rhone-Poulenc. 63 p. {OPPTS 860.1500}

44792026 Maestracci, M. (1997) Phosalone: Formulation EXP05531D (EC) Trial France 1996 Residues in Apple Decline Study: Lab Project Number: 96-776: RD/CRLD/ANVT9716613. Unpublished study prepared by Rhone-Poulenc. 60 p. {OPPTS 860.1500}

44792027 Maestracci, M. (1998) Phosalone: Formulation EXP05531D (EC) Trials France 1997 Residues in Apple: Lab Project Number: 97-602: RD/CRLD/AN/VT9815382. Unpublished study prepared by Rhone-Poulenc. 50 p. {OPPTS 860.1500}

44792028 Maestracci, M. (1998) Phosalone: Formulation EXP05531D (EC) Trials France 1997 Residues in Apple: Reverse Curve: Lab Project Number: 97-601: RD/CRLD/ANDBE9815324. Unpublished study prepared by Rhone-Poulenc. 66 p. {OPPTS 860.1500}

44792029 Maestracci, M. (1998) Phosalone: Formulation EXP60308B (WP) Trial Spain 1997 Residues in Pear: Reverse Curve: Lab Project Number: 97-702: RD/CRLD/AN/VT9815818. Unpublished study prepared by Rhone-Poulenc. 50 p. {OPPTS 860.1500}

- 44792030 Maestracci, M. (1998) Phosalone: Formulation EXP60308B (WP) Trial Italy 1997 Residues in Apple: Lab Project Number: 97-264: RD/CRLD/ANVT9815916. Unpublished study prepared by Rhone-Poulenc. 84 p. {OPPTS 860.1500}
- 44792031 Maruyama, M. (1979) Phosalone: Report on Pesticide Residue Analysis: Official Trials Apple: Lab Project Number: PHOS/JAPAN/1979/1RPA. Unpublished study prepared by Chuo University. 21 p. {OPPTS 860.1500}
- 44792032 Kato, M. (1979) Phosalone: Report on Pesticide Residue Analysis: Official Trials Apple: Lab Project Number: PHOS/JAPAN/1989/1RPA. Unpublished study prepared by Japan Food Analysis Federation. 18 p. {OPPTS 860.1500}
- 44792033 Maestracci, M. (1998) Phosalone: Formulation EXP60308B (WP) Trials Germany 1997 Apple and in Pear Reverse Curve: Lab Project Number: 97-767: RD/CRLD/ANMSA9816476. Unpublished study prepared by Rhone-Poulenc. 117 p.
- 44792034 Muller, M. (1999) Phosalone: Formulation: Zolone 25L (EC) Tests in Italy, 1989 Residues in Leaves and Fruit of Grapes: Lab Project Number: AG/CRLD/AN/9015907. Unpublished study prepared by Rhone-Poulenc. 22 p.
- 44792035 Maestracci, M. (1997) Phosalone: Formulation EXP06027B (SC) Trials France 1996 Residues in Cherry: Decline Study: Lab Project Number: 96-542: RD/CRLD/ANDBE9716189. Unpublished study prepared by Rhone-Poulenc. 81 p.
- 44792036 Maestracci, M. (1998) Phosalone: Formulation EXP05531D (EC) Trial France 1997 Residues in Peach Reverse Curve: Decline Study: Lab Project Number: 97-522: RD/CRLD/ANDBE9815342. Unpublished study prepared by Rhone-Poulenc. 52 p. {OPPTS 860.1500}
- 44792037 Maestracci, M. (1998) Phosalone: Formulation EXP05531D (EC) Trial France 1997 Residues in Cherry: Decline Study: Lab Project Number: 97-554: RD/CRLD/AN/VT9815381. Unpublished study prepared by Rhone-Poulenc. 93 p. {OPPTS 860.1500}
- 44792038 Maestracci, M. (1998) Phosalone: Formulation EXP05531D (EC) Trial France 1997 Residues in Peach: Lab Project Number: 97-523: RD/CRLD/AN/VT9815817. Unpublished study prepared by Rhone-Poulenc. 52 p. {OPPTS 860.1500}
- 44792039 Maestracci, M. (1998) Phosalone: Formulation EXP60308B (WP) Trial Italy 1997 Residues in Peach: Decline Study: Lab Project Number: 97-622: RD/CRLD/ANDBE9815848. Unpublished study prepared by Rhone-Poulenc. 87 p. {OPPTS 860.1500}
- 44792040 Maestracci, M. (1998) Phosalone: Formulation EXP60308B (WP) Trial Spain 1997

Residues in Peach: Lab Project Number: 97-701: RD/CRLD/ANDBE981532. Unpublished study prepared by Rhone-Poulenc. 48 p. {OPPTS 860.1500}

44792041 Muller, M. (1995) Phosalone and oxo-Phosalone (Metabolite) Formulation EXP 06027A (SC) Trials France 1994 Residues in Almond: Lab Project Number: 94-543: RD/CRLD/AN/BD9516513. Unpublished study prepared by Rhone-Poulenc. 56 p. {OPPTS 860.1500}

44792042 Maestracci, M. (1997) Phosalone: Formulation EXP05531D (EC) Trial France 1996 Residues in Almond: Lab Project Number: 96-528: RD/CRLD/ANDBE9716150. Unpublished study prepared by Rhone-Poulenc. 52 p.

44792043 Maestracci, M. (1997) Phosalone: Formulation EXP06027B (SC) Trial France 1996 Residues in Almond: Decline Study: Lab Project Number: 96-529: RD/CRLD/ANDBE9716188. Unpublished study prepared by Rhone-Poulenc. 55 p. {OPPTS 860.1500}

44792044 Maestracci, M. (1997) Phosalone: Formulation EXP05531D (EC) Trial France 1996 Residues in Almond: Decline Study: Lab Project Number: 96-530: RD/CRLD/ANDBE9716168. Unpublished study prepared by Rhone-Poulenc. 55 p. {OPPTS 860.1500}

44792045 Maestracci, M. (1997) Phosalone: Formulation EXP06027B (SC) 96-525: RD/CRLD/AN/KD9716028. Unpublished study prepared by Rhone-Poulenc. 52 p. {OPPTS 860.1500}

44792046 Maestracci, M. (1999) Phosalone: Formulation EXP06027B (SC) Residues in Apple and Processed Products: Trial France 1996: Lab Project Number: 96-694: RD/CRLD/ANDBE9816999. Unpublished study prepared by Rhone-Poulenc. 59 p. {OPPTS 860.1520}

Phosalone and its metabolites in plants.

Common Name (Number)	Structure
Phosalone (RP 11974)	
Oxophosalone (RP 12244)	
Deschlorophosalone (RP 11690)	
6-chlorobenzoxazolone (RP 11881) ¹	
Benzoxazolone (LS 600174)	
2-amino-5-chlorophenol (RP 18709)	

¹ The 3-(N-glucoside) and 3-(N-saccharide) of 6-chlorobenzoxazolone were also identified in grapes.